GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1211
ANSWERED ON:08.12.2004
CLINICAL TRIAL BY BIOTECH COMPANY
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a major Biotech Company had been conducting clinical trials on their experimental drugs, Insulin, without the approval of Genetic Engineering Approval Committee (GEAC) as appeared in Economic Times dated September 26, 2004 ;

(b) if so, whether some deaths took place at the time of its development and trial;

(c) if so, the details of the case and name of the company involved ; and

(d) the action taken/being taken by the DCGI against the company ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) All Biotech Companies indigenously producing recombinant human insulin have to obtain necessary permission for undertaking clinical trial from the office of Drugs Controller General of India as per norms stipulated under Drugs & Cosmetics Act and rules made thereunder.

Approval of Genetic Engineering Approval Committee (GEAC) is also required for safe release of genetically engineered drugs into environment, as per the rules framed under the Environmental Protection (EP) Act 1986, issued by Min. of Environment & Forests.

Not taking prior approval from GEAC by M/s. Biocon India Ltd. Bangalore, for its indigenously development r-human insulin, at the stage of clinical trial, has been considered as a procedural lapse and therefore ex-post-facto GEAC approval has been accorded for conducting phase III clinical trial and permission for its manufacture and market, by the Ministry of Environment & Forest vide their letter dated 19th July, 2004.

(b) There is no specific report of any death having occurred during the time of development and clinical trial involving r-human insulin of M/s Biocon India Ltd. Bangalore.

(c)&(d): Question does`t arise.